INTRODUCTION

The NIH Clinical Center strives to provide a safe environment for employees, patients, and visitors. Our employees are trained for their jobs. Hazard surveillance is conducted routinely to identify unsafe practices, equipment, or facilities. When identified, hazards are eliminated or measures are instituted to reduce the risk whenever possible.

Tuberculosis (TB) has plagued human kind since ancient times. It is caused by an organism called *Mycobacterium tuberculosis*. Beginning in 1945, when antibiotics that could kill the tuberculosis organism were discovered, TB could finally be cured and the number of infected persons decreased dramatically. In recent years, however, tuberculosis has reemerged as an important public health threat. In the late 1980s and early 1990s several hospital outbreaks of TB occurred, involving strains that were resistant to many of the antibiotics used to treat TB. These strains, called "multi-drug-resistant TB" (MDR-TB) are much more difficult to treat, require longer treatment periods with drugs that have more toxic side effects, have a lower cure rate, and often progress very rapidly and have a higher fatality rate, especially in persons infected with the human immunodeficiency virus (HIV).

Health care workers need to know that TB can be transmitted from patient to patient, from patient to health care worker, from health care worker to patient and from health care worker to health care worker.. There are many reasons for the hospital outbreaks that have occurred, but transmission is most likely to occur from patients who have unrecognized pulmonary or laryngeal TB, are not on effective anti-TB therapy, and have not been placed in TB isolation. Transmission to HIV-infected persons is of particular concern because these persons are at high risk of developing active TB if they become infected.

This Tuberculosis Infection Control Plan has been developed in response to both the Centers for Disease Control and Prevention's (CDC) "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994" and the Clinical Center's concerns for patient and employee safety. The plan is designed to help health care workers safeguard their own health, their co-workers' health, and their patients' health. It is vital that every employee with occupational exposure to tuberculosis understands how tuberculosis is transmitted and the safety policies and procedures described within this document. Health care workers must know

about TB and how its spread can be prevented. They need to know which patients should be tested, who has an active case and is contagious, how to isolate infectious patients and how to ensure their own and other's safety.

An effective TB infection control program requires early identification, isolation, and treatment of persons who have active TB. These three goals should be achieved by applying a hierarchy of control measures, including:

- **administrative controls** to reduce the risk of exposure to persons who have infectious TB (these include policies and procedures to rapidly identify, isolate and evaluate patients likely to have TB; ensuring that HCWs receive education and training about TB and that they comply with effective work practices, such as keeping isolation room doors closed and wearing respiratory protective equipment properly; and screening HCWs regularly for TB infection and/or disease);
- **engineering controls** to prevent the spread and reduce the concentration of infectious droplet nuclei (these include proper ventilation and airflow direction, and dilution and removal of contaminated air from the TB source); and
- **personal respiratory protective equipment** to be used in areas where there is still a risk for exposure to TB despite administrative and engineering controls (e.g., TB isolation rooms, sputum induction and bronchoscopy rooms).

Implementation of a TB control program involves risk assessment and development of a TB control plan; early identification, treatment, and isolation of infectious TB patients; effective engineering controls; an appropriate respiratory protection program; health-care worker TB training, education, counseling, and screening; and evaluation of the program's effectiveness. Although completely eliminating the risk of TB transmission may not be possible at the present time, adherence to the CDC guidelines should reduce the risk to workers and patients in the CC.

To aid employees in understanding who is at occupational risk for TB in the CC, the TB Infection Control Plan contains a section (III) entitled "EMPLOYEES WITH POTENTIAL FOR OCCUPATIONAL RISK FOR TB". This section explains how the Clinical Center identifies health-care workers who must participate in the Occupational Medical Service's Tuberculosis Surveillance Program.

I. ASSIGNATION OF RESPONSIBILITY FOR SUPERVISING THE DEVELOPMENT, IMPLEMENTATION, EVALUATION, AND MAINTENANCE OF THE TB INFECTION CONTROL PROGRAM:

The CC Deputy Director for Clinical Care and Associate Director for Quality Assurance and Hospital Epidemiology (Hospital Epidemiologist) is responsible for supervising the development, implementation, evaluation, and maintenance of the TB infection control program. Beginning in March, 1993, a CC TB Prevention Task Force began meeting to develop this program. Members included the Deputy Director for Clinical Care and Hospital Epidemiology, the Hospital Epidemiology Service, the CC Environmental Safety Officer, and ad hoc representatives from Office of Facility Management and the Occupational Medical Service. Over 25 different elements were identified that needed to be developed to achieve a comprehensive control program. Members of the Task Force formed various subcommittees and sought CC and institute expertise to develop the various protocols of the control program. Individual protocols were implemented as development progressed over time. The specific methods instituted for each of the plan's elements are described in the designated sections herein. The program will be evaluated and modified as needed. Originally, formal review and approval of the final plan was awaiting the publication of regulations by the Department of Labor's Occupational Safety and Health Administration (OSHA). However, following publication of OSHA's proposed rule in October, 1997 (29 CFR Part 1910), over 1,300 submissions of comments to the agency means a lengthy review process will further delay the OSHA final rule. The entire plan was formally reviewed by the CC Hospital Infections Committee on November 24, 1998 and will be reviewed on an annual basis thereafter.

II. AVAILABILITY OF THE TB INFECTION CONTROL PLAN:

The Clinical Center makes the TB Infection Control Plan available for review to all employees. It is located in the Hospital Epidemiology Service, Bldg. 10 Rm. 10S 239.

III. EMPLOYEES WITH POTENTIAL FOR OCCUPATIONAL RISK FOR TB:

In their 1994 guidelines to prevent transmission of TB in health-care facilities, the CDC defines health-care workers (HCWs) as "…all the paid and unpaid persons working in health-care settings who have the potential for exposure to *M. tuberculosis*. This may include, but is not limited to, physicians; nurses; aides; dental workers; technicians; workers in laboratories and morgues; emergency medical service (EMS) personnel; students; part-time personnel; temporary staff not employed by the health-care facility; and persons not involved directly in patient care but who are potentially at risk for occupational exposure to *M. tuberculosis* (e.g., volunteer workers and dietary, housekeeping, maintenance, clerical, and janitorial staff)."[1] Using this definition, the CC defines "persons…who have the potential for exposure to *M. tuberculosis*" to include persons who routinely have patient contact or who enter patient rooms or examination or treatment rooms, but does not include persons whose only contact with patients is in elevators, the cafeteria, or other public areas. Persons who are exposed to *M. tuberculosis* in a laboratory or morgue, or who work in a primate animal care setting are also included, as are persons who are credentialed for patient care.

CC employees with potential for occupational exposure are identified by their department heads, institute employees are identified by their clinical directors. Employees credentialed for patient care are identified by the Credentialing Office of the Medical Records Department. Employees with potential for occupational risk for TB must be enrolled in a tuberculosis screening program. The NIH Occupational Medical Service (OMS) conducts tuberculosis screening for NIH employees; contract employees' screening must be provided by their contractor according to the CDC guidelines, and the results reported to the HES as requested, for the CC periodic risk assessment.

[1] Centers for Disease Control and Prevention, Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care facilities, 1994. MMWR 1994;43(No. RR-13): p. 9.

IV. RISK ASSESSMENT

A. Definitions of Risk Categories

Definitions for the CDC risk categories that apply to an entire health care facility, a specific area in the facility, or occupational groups within the facility, based on the initial and periodic risk assessments, are:

Minimal Risk: This category applies only to an entire facility. A "minimal-risk" facility does not admit TB patients to inpatient or outpatient areas and is not located in a community with TB (i.e., counties or communities in which TB cases have not been reported during the previous year). Thus, there is essentially no risk for exposure to TB patients in the facility.

Very Low Risk: This category generally applies only to an entire facility. A "very low-risk" facility is one in which a) patients with active TB are not admitted to inpatient areas but may receive initial assessment and diagnostic evaluation or outpatient management in outpatient areas and b) patients who may have active TB and need inpatient care are promptly referred to a collaborating facility. In such facilities, the outpatient areas in which exposure to patients with active TB could occur should be assessed and assigned to the appropriate low-, intermediate-, or high-risk category. Categorical assignment will depend on the number of TB patients examined in the area during the preceding year and whether there is evidence of nosocomial transmission of *M. tuberculosis* in the area. If TB cases have been reported in the community, but no patients with active TB have been examined in the outpatient area during the preceding year, the area can be designated as very low risk.

Low Risk: This category applies to areas or occupational groups in which a) the PPD test conversion rate is not greater than that for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or group, b) no clusters of PPD test conversions have occurred (i.e., two or more PPD skin-test conversions occurring within a 3-month period among HCWs in a specific area or occupational group, and epidemiologic evidence suggests occupational [nosocomial] transmission), c) person-to-person transmission of *M. tuberculosis* has not been detected, and d) fewer than six TB patients are examined or treated per year.

Intermediate Risk: This category applies to areas or occupational groups in which a) the PPD test conversion rate is not greater than that for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or group, b) no clusters of PPD test conversions have occurred, c) person-to-person transmission of *M. tuberculosis* has not been detected, and d) six or more patients with active TB are examined or treated each year. Survey data suggest that facilities in which six or more TB patients are examined or treated each year may have an increased risk for transmission of *M. tuberculosis*.

High Risk: This category applies to areas or occupational groups in which a) the PPD test conversion rate is significantly greater than for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or group, and epidemiologic evaluation suggests nosocomial transmission; **or** b) a cluster of PPD test conversions has occurred, and epidemiologic evaluation suggests nosocomial transmission of *M. tuberculosis* is; **or** c) possible person-to-person transmission of *M. tuberculosis* has been detected, and d) six or more patients with active TB are examined or treated each year

B. Classifying Risk Levels

Classifying the level of risk for the entire CC, specific areas in the CC, and specific occupational groups in the CC (including those whose work takes them throughout the hospital, for example, respiratory therapists, phlebotomists, dietary and maintenance staff) is based on:

- the community's TB profile;
- the number of contagious TB patients admitted to an area or the estimated number of contagious TB patients who have been in contact with health care workers in an occupational group; and
- the analyzed results of health care worker's PPD test conversions and possible person-to-person transmission of *M tuberculosis*.

C. Initial Risk Assessment

1. Clinical Center Background

The Clinical Center is a unique hospital. Our facility lacks some of the features of other hospitals that are associated with increased risk for TB infection: we have no emergency room and our patients do not come "off the street" from local communities. Our patients are referred by other health-care providers, usually after extensive preadmission medical evaluations, to participate in specific research protocols. On the other hand, our patients include many who have HIV infection, are immunosuppressed, or have other conditions that may predispose them to active TB infection. The number of TB patients in our hospital will vary with the activity of protocols for patients known to have MDR-TB or patients at high risk for TB. Until the advent of protocols to study MDR-TB, tuberculosis had been a rare event in the CC.

2. Elements of Risk Assessment

The main elements of the risk assessment, from the CDC guidelines, are presented in Table 1. A more detailed description of these elements, with recommendations according to risk levels, may be found in Figure 1 from the CDC guidelines, in Appendix A.

3. Community TB Profile

A baseline risk assessment to evaluate the risk for transmission of *M. tuberculosis* in the Clinical Center was begun in 1993 and was reassessed periodically as more data became available and as protocols for TB patients were activated. All elements of the risk assessment protocol outlined in the CDC 1994 guidelines are not as applicable to the Clinical Center as they would be to a community hospital. For example, reviewing the community TB profile from public health department data would not reflect the "catchment area" for patients admitted to the Clinical Center. We performed a point prevalence study of CC patients in April 1996. There were over 34,000 patients in active status at the CC. Over 750 were from foreign countries, ≈19,000 were from local city/states (Maryland, Virginia, and the District of Columbia), and over 14,000 were from the other 48 states. Maryland was the state with the single largest contribution (≥11,700 patients).

Recognizing the limitations of applying a community TB profile to the CC, we nonetheless obtained data regarding TB incidence and rates from the Maryland Division of Tuberculosis and Control and the Montgomery County Health Department. For several years, over 80% of TB cases in Montgomery County have occurred in foreign born individuals. In 1995, only one of 102 cases was MDR-TB and 13% had some drug resistance; no treatment problems occurred. These data are included in Appendix B. Because TB has been present in the community, the "minimal risk" category is inappropriate for the CC.

4. Case Surveillance of TB Patients

As part of the initial risk assessment, laboratory data, medical records and infection control records were retrospectively reviewed from January 1989 to obtain the number of patients and health-care workers with TB in the CC; a graph of the incidence is included in Appendix B. The risk factors, history, drug susceptibility and hospital course for each patient diagnosed with pulmonary or laryngeal TB were summarized and are on file in the HES office. (Although included in the counts, descriptive summaries were not completed on TB-protocol patients). Fewer than six TB patients were examined or treated in the CC per year, and the "low risk" category was appropriate, until the fourth quarter of 1995. The increase in TB patients beginning in 1995

was due primarily to TB research protocols, where patients known to have TB are admitted directly to TB isolation rooms.

5. PPD Test Conversions and Person-to-Person Transmission

For the initial risk assessment, only case reports of PPD conversions were available, as PPD testing results were recorded in employee medical records and on file cards, and were not available in a retrievable database where denominators could be determined. OMS reviewed PPD data from 1992 until the retrievable database was instituted in May 1995, and identified 12 potential or documented PPD conversions. The number of potential and documented PPD conversions were examined by quarter and by circumstances of conversion (e.g., if conversion was detected on initial PPD [considered potential conversion], a follow-up [recall] PPD [documented conversion], and after contact with a patient with TB [documented conversion]). These data are displayed in a graph in Appendix B. There was a cluster of 4 PPD conversions in late 1992 and early 1993 attributed to exposures to a single immunosuppressed patient who was not isolated for 3 days until a TB diagnosis was suspected; one of these (late 1992) occurred in an employee who had no prior PPD testing at OMS and was classified as a potential conversion. Two other conversions were associated with contact with a TB patient in April 1995; these workers had no prior PPD testing at OMS and were classified as potential conversions. In August 1993 one worker had a documented conversion on routine PPD testing, but had no documented exposure to a known TB patient. Potential conversions also occurred in late 1992 (1), July 1993 (1), June 1994 (1), and January 1995 (2) among workers who had no known contact with TB patients and no prior PPD test at OMS.

D. Periodic Risk Assessment

1. Community TB Profile

Again, recognizing the limitations of applying the community TB profile to the CC, because Maryland is the predominant state from which our patients come, we obtain data regarding TB incidence and rates and drug susceptibility profiles from the Maryland Division of Tuberculosis and Control and the Montgomery County Health Department on an annual basis. These data are on file in the Hospital

Epidemiology Service office. Because TB is, and most likely will continue to be present in the community, the "minimal risk" category will likely remain inappropriate for the CC.

2. Case Surveillance of TB Patients

Using the CDC guidelines for periodic risk assessments, we continue to prospectively and systematically collect data on TB patients in the CC. Data are collected from laboratory surveillance data on specimens positive for AFB smears or *M. tuberculosis* cultures, and from infection control records. Similarly to the baseline risk assessment, the risk factor, history, drug susceptibility and hospital course for each patient diagnosed with pulmonary or laryngeal TB are collected and summarized. Data collection forms used by infection control personnel are included in Appendix B. This information is updated quarterly and is on file in the Hospital Epidemiology Service office. (Although included in counts, descriptive summaries of TB-protocol patients are not included). These data are reviewed to estimate the number of TB isolation rooms needed, to recognize possible clusters of nosocomial transmission, and to assess the level of potential occupational risk.

3. PPD Test Conversions and Person-to-Person Transmission

The NIH Occupational Medical Service revised and improved the employee PPD screening program in May 1995. Results of PPD testing continue to be recorded in the individual HCW's employee health record. The file card system was replaced by a computerized aggregate database retrievable by area or occupational group. This enables us to calculate PPD test conversion rates by each area of the hospital and for each specific occupational group. Test conversion rates are compared with those rates from areas or occupational groups in which TB exposure is unlikely and with previous conversion rates from the same group or area. These comparisons will reveal where occupational risks for TB transmission may have occurred and indicate where epidemiologic investigations should be done to determine occupational transmission of *M. tuberculosis*. Reports are routinely done every six months, April–September and October–March, and can be done more frequently if appropriate. PPD test conversion rates are calculated for each area of the facility and for each specific occupational group not assigned to a specific area. To calculate PPD test conversion rates, the

total number of previously PPD-negative HCWs tested in each area or group (i.e., the denominator) and the number of PPD test conversions among HCWs in each area or group (the numerator) are obtained. Beginning in 1996, contractors with employees in Bldg. 10 who have potential occupational exposure to TB, are required to PPD screen their employees according to the CDC's 1994 guidelines, and report the results to the HES as requested, for inclusion in the periodic risk assessment.

The frequency and comprehensiveness of the HCW PPD testing program are evaluated periodically to ensure that all HCWs who should be included in the program are being tested at appropriate intervals. Results of the periodic PPD conversion rates are filed in the HES office.

If either PPD test conversions or active TB in a HCW is noted, OMS contacts the HES and an epidemiologic investigation to evaluate the likelihood of nosocomial transmission is conducted (see Section XI). Contact exposure studies are also conducted if possible person-to-person transmission of TB has occurred, in situations in which a patient or HCW with active TB is not promptly identified and isolated, or when breaks in isolation are identified. These epidemiologic investigations and TB contact exposure studies are reported to the Hospital Infections Committee.

4. Review of TB Patient Medical Records

The medical records of all patients with suspected or confirmed TB who require AFB Isolation are reviewed to evaluate the effectiveness of infection control procedures and TB treatment. The parameters evaluated include:

1) time from admission until:
   a) TB suspected and isolation initiated,
   b) AFB specimens ordered;
2) time from AFB specimens ordered until:
   a) AFB smears performed and reported,
   b) AFB cultures performed and reported,
   c) AFB species identification performed and reported,
   d) drug susceptibility tests performed and reported;
3) time from admission until:
   a) TB treatment initiated;
4) duration of isolation;

5) adequacy of TB treatment regimen;
6) history of admission to the CC;
7) appropriate criteria used to discontinue isolation; and
8) appropriate discharge planning was conducted.

Data from these case reviews are used to determine if there is a need to modify a) protocols for identifying and isolating patients who may have infectious TB, b) laboratory procedures, c) administrative policies and procedures, or d) protocols for patient management. Data collection forms and summaries are included in Appendix B.

5. Observation of TB Infection Control Practices

The HES periodically conducts assessments of HCW and patient adherence to the policies and procedures of the TB infection control program. This assessment is performed on a regular basis and whenever an increase occurs in the number of TB patients or HCW PPD test conversions. Areas at high risk for transmission of *M. tuberculosis* are monitored more frequently than other areas. The review of patient medical records provides information on HCW adherence to some of the policies of the TB infection-control program. In addition, work practices related to TB isolation (e.g., keeping doors to isolation rooms closed) are observed to determine if CC staff are enforcing, and HCWs are adhering to, these policies and if patient adherence is being enforced. While on surveillance, infection control specialists routinely observe if TB isolation room doors are kept closed. Keeping doors to isolation rooms closed is also monitored continuously by airflow monitors. If these policies are not being enforced or adhered to, appropriate education and other corrective action is implemented.

6. Engineering Evaluation

Working closely with the CC Environmental Safety Officer and staff from the Office of Facility Management, numerous design and engineering modifications have been made in order to upgrade areas of the CC where infectious TB patients receive care. Isolation rooms have been constructed to meet criteria for isolation rooms (negative pressure, minimum 6 air changes/hour, air exhausted to outdoors, no recirculation by means of room units).[2] Other specific rooms throughout the CC have

[2] HHS Guidelines for Construction & Equipment of Hospitals/Medical Facilities, 1992–

been modified to achieve negative airflow, and aerosol treatment enclosures are used to contain infectious aerosols. An updated listing of isolation rooms and specially modified treatment rooms is maintained in consultation with the CC Environmental Safety Officer and the Office of Facility Management and is included in Appendix C. Most of these rooms are equipped with continuous pressure monitors to ensure that negative pressure is maintained. If the pressure monitor is defective, maintenance confirms the directional airflow using a smoke stick test prior to use for a patient with suspected or confirmed tuberculosis. Maintenance may also check the number of air changes per hour and balancing parameters to indicate and check the operation of the monitor. These reports are on file in the Hospital Epidemiology Service office, the CC Safety Office, and Office of Facility Management. The CC Maintenance and Engineering Section also perform routine maintenance and inspections of the CC ventilation system. Their preventative maintenance and inspection procedures are included in Appendix L.

HEPA filters are used when one-pass air is not available to protect employees from potential exposure to TB. In addition, the Department of Laboratory Medicine, Microbiology Laboratory, has a certified BSL3 facility for processing specimens that could contain viable infectious organisms. Respiratory Therapy also has a booth with HEPA filters used for sputum induction or administration of aerosolized medications. These rooms with HEPA filters in exhaust ducts, biological safety cabinets, or enclosing booths are identified in the room listing in Appendix C. The HEPA filters in these systems are monitored yearly through the NIH Division of Safety Occupational Safety and Health Branch. Reports are reviewed by the HES and the CC Environmental Safety Officer.

Although considered personal respiratory protective devices, to ensure optimal performance of powered air-purifying particulate respirators (PAPRs), the Biomedical Engineering Section of the CC Materials Management Department performs maintenance on PAPRs annually (inspection, performing airflow tests, replacing HEPA filters and installing new batteries). As part of the periodic risk assessment, data from the most recent maintenance procedures and logs are reviewed.

3.

E. Development of the TB Infection Control Plan

Based on the results of the initial risk assessment, this written TB infection control plan was developed and implemented. Most areas of the CC are minimally classified as “low-risk.” However, with the activation of MDR-TB research protocols in 1995, over six TB patients were admitted to the CC each year. Therefore, some areas in which six or more patients with active TB are examined or treated each year (or occupational groups in which HCWs are likely to be exposed to six or more TB patients per year) are classified at a minimum as “intermediate-risk.” Our TB control plan follows the CDC’s recommended elements and protocols as outlined in Table 1 of Appendix A. Areas in which cough-inducing procedures are performed on patients who may have active TB are considered “intermediate-risk” at a minimum. Further details are explained in the following sections.

F. Periodic Reassessment

Follow-up risk assessments are performed by the HES at the interval indicated by the most recent risk assessment (Fig. 1). Based on the baseline risk assessment (low risk category), the overall facility re-assessment will initially be conducted annually. Areas and occupations considered intermediate risk will initially be conducted every six months. Areas and occupations considered intermediate risk at a minimum *a priori* may include employees who:

- work in the Mycobacteriology Lab or who work with MTB cultures;
- perform bronchoscopies;
- perform respiratory therapy or cough-inducing procedures;
- work in the Pulmonary Lab;
- work with immunosuppressed patients in the bone marrow transplant unit or medical intensive care unit;
- work with nonhuman primates.

Based on the results of the follow-up assessments, problem evaluation may need to be conducted or the protocol may need to be modified to a higher- or lower-risk level.

After each risk assessment, the HES, in conjunction with other appropriate CC staff, reviews the TB control policies to ensure that they are effective and meet current needs.

V. EARLY IDENTIFICATION, DIAGNOSTIC EVALUATION, AND EFFECTIVE TREATMENT OF PATIENTS WHO MAY HAVE CONTAGIOUS TB

The first critical step in preventing transmission of *M. tuberculosis* is the early identification of patients who may have infectious TB, so that TB isolation precautions can be implemented promptly, and effective treatment can begin.

A. Identification of Patients Who May Have Active TB

The CC has developed several mechanisms designed to help us identify, as early as possible, patients who may have active TB. Because our patients are admitted to research protocols, the HES reviews CC protocols on a routine basis, to identify protocols either specifically admitting patients with tuberculosis, or protocols whose patients might be at high risk for having active tuberculosis. The search is done both manually and electronically. Manually, the HES maintains a Protocol Directory Institute Listing published by the CC MRD Protocol Services Section, which is updated and reviewed periodically. A search can also be performed electronically. The HES searches the electronic database of current NIH protocols, using keywords designed to help detect protocols that may be enrolling patients with suspected or diagnosed pulmonary tuberculosis, or patients at high risk of tuberculosis. Instructions detailing this procedure are included in Appendix D. Information on current protocols thus identified, including principal investigator, precis, and other information, is kept in the HES binder labeled “NIH CC TB Protocols”. Once a protocol is identified, the principal investigator is contacted to offer HES services to facilitate implementation of isolation procedures. Patients in these identified protocols with known or suspected TB are then admitted to the CC under special arrangements, essentially being isolated “from door-to-door.” See “Guidelines for Management of Tuberculosis Inpatient Admission: Patients with Known or Suspected Pulmonary or Laryngeal Tuberculosis” in Appendix E.

For patients with known or suspected TB who are not identified prior to admission, the second mechanism for identifying patients with TB takes place when the patient has their initial encounter at Admissions or the Outpatient Department. Signs are posted in Admissions, outpatient clinics, phlebotomy, radiation oncology, and various diagnostic areas. Self screening for symptoms of active TB includes: cough for ≥ 3 weeks without known

cause and one of the following: bloody sputum, night sweats, fever, or weight loss without known cause. If the patient has symptoms, the responsible health care worker will immediately place the patient in a private room (negative pressure isolation room, if available) and notify the Hospital Epidemiology Service. See Appendix F for further details regarding the triage system. HES staff will obtain a targeted medical history and risk factors for TB. If the patient has one or more medical history or risk factors for TB, the patient is immediately placed on AFB Isolation and a diagnostic evaluation is begun. Further details are included in "Guidelines for the Identification, Diagnosis and Initial Treatment of Patients With Tuberculosis" in Appendix G and in Section V.D.: "Managing Patients Who May Have Active TB in Ambulatory Care Settings."

As part of the periodic risk assessment, we review the medical records of patients who were examined in the CC and diagnosed as having TB to see if our protocols to identify patients with active TB need to be revised.

B. Diagnostic Evaluation of Patients Who May Have Active TB

In addition to a medical history and physical examination, diagnostic tests for identifying TB are performed in consultation with the Infectious Disease Service and the Hospital Epidemiology Service. Tests include a chest x-ray (ordered to "r/o TB"), PPD testing (with anergy panel if HIV+) and three sputa for AFB culture and smears on three different days. Further details are included in "Guidelines for the Identification, Diagnosis and Initial Treatment of Patients With Tuberculosis" in Appendix G. Other diagnostic procedures (e.g., bronchoscopy or biopsy) may be indicated for some patients.

The Microbiology Service of the Department of Laboratory Medicine is proficient at both the technical and administrative aspects of mycobacteriologic specimen processing and testing. Tests routinely used include:

- fluorescent microscopy for AFB smears
- radiometric culture methods for isolation of mycobacteria
- nucleic acid probes for MTB complex and nitrate/niacin tests in order to identify as *M. tuberculosis*

Specimens for AFB culture and AFB smear are processed every workday. Specimens submitted on weekends or holidays are not routinely processed until the next regular working day. However, STAT AFB smears can be

performed at any time with Senior Staff approval. If ordered STAT, results of AFB sputum smears are available within 6 hours of specimen collection.

Isolates of *M. tuberculosis* are referred for susceptibility testing to the Maryland State Laboratory in Baltimore as soon as possible after they are identified. Radiometric methods are used for susceptibility testing. Antibiotic sensitivities are routinely performed on the first isolate of *M. tuberculosis* identified from each patient

The probability of TB is greater among patients who: 1) have positive PPD test results or a history of positive PPD test results; 2) have previously had TB or have been exposed to *M. tuberculosis*, or 3) belong to a group at high risk for TB. Groups at higher risk for TB include:

- foreign-born persons from areas of the world with a high prevalence of TB (e.g., Asia, Africa, the Caribbean, and Latin America),
- persons from areas in the U.S. with a high prevalence of TB (e.g., New York City-Newark, San Francisco-Oakland, Honolulu, Houston, Santa Ana-Los Angeles)
- medically underserved populations (e.g., some African-Americans, Hispanics, Asians and Pacific Islanders, American Indians, and Alaskan Natives),
- homeless persons,
- current or former correctional-facility inmates,
- alcoholics,
- injecting-drug users, and
- the elderly.

Groups at a higher risk for progression from latent TB infection to active disease include:

- persons who have been infected recently (i.e., within the previous 2 years),
- children <4 years of age,
- persons with fibrotic lesions on chest radiographs, and
- persons with certain medical conditions (i.e., HIV infection, silicosis, gastrectomy or jejuno-ileal bypass, being ≥10% below ideal body weight, chronic renal failure with renal dialysis, diabetes mellitus, immunosuppression resulting from receipt of high-dose corticosteroid or other immunosuppressive therapy, leukemia or lymphoma).

Active TB is strongly suggested if the diagnostic evaluation reveals AFB in sputum, a chest radiograph suggestive of TB, or symptoms highly suggestive

of TB. TB can occur simultaneously in immunosuppressed persons who have pulmonary infections caused by other organisms (e.g., *Pneumocystis carinii* or *Mycobacterium avium* complex) and should be considered in the differential diagnosis of all patients who have symptoms compatible with TB. Further details of the diagnostic evaluation process are included in "Guidelines for the Identification, Diagnosis and Initial Treatment of Patients With Tuberculosis" in Appendix G.

TB may be more difficult to diagnose among persons who have HIV infection or other conditions with severe suppression of cell-mediated immunity because of a nonclassical clinical or radiographic presentation and/or coinfections with other agents. The difficulty in diagnosing TB in HIV-infected persons may be further compromised by impaired responses to PPD skin tests, the possibly lower sensitivity of sputum smears for detecting AFB, or the overgrowth of cultures with *Mycobacterium avium* complex.

Immunosuppressed patients who have pulmonary signs or symptoms that are ascribed initially to infections or conditions other than TB should also be evaluated for coexisting TB. The evaluation for TB should be repeated if the patient does not respond to appropriate therapy for the presumed cause of the pulmonary problem.

Patients with suspected or confirmed TB are immediately placed in AFB Isolation and if TB is highly suspected or confirmed the patients are reported to the public health department. Patients for whom TB is ruled out are released from isolation.

C. Treatment of Patients Who Have Active TB

Patients with confirmed or highly suspected TB receive prompt treatment. The regimen options as recommended by the CDC Guidelines are implemented, in consultation with the Infectious Disease Service. Further details are included in "Guidelines for the Identification, Diagnosis and Initial Treatment of Patients With Tuberculosis" in Appendix G. An initial regimen including four drugs is usually recommended, and the regimen may be adjusted when drug-susceptibility results are available. The regimen is currently based on the baseline risk assessment finding that our geographic area does not have a high prevalence of MDR-TB. For patients with MDR-TB in MDR-TB protocols, experimental regimens are implemented as part of the research protocol. Should a non-MDR-TB-protocol patient be identified with MDR-TB, the treatment regimen will be implemented in

consultation with the Infectious Disease Service. For patients coinfected with HIV, the most recent CDC recommendations for treatment regimens should be consulted (Appendix S). All anti-TB medications given in the CC are administered by directly observed therapy (DOT). Arrangements are made with the public health department before discharge to ensure that treatment is continued by outpatient DOT programs.

D. Managing Patients Who May Have Active TB in Ambulatory Care Settings

For TB patients not identified through protocol mechanisms, we have other mechanisms to promptly identify patients with signs and symptoms suggestive of active TB. The CC does not have an emergency room, so triage for identifying patients with TB takes place when the patient has their initial encounter at Admissions or the Outpatient Department. As previously detailed, self screening for symptoms is performed: cough for $\geq$ 3 weeks without known cause and one of the following: bloody sputum, night sweats, fever, or weight loss without known cause. If the patient has symptoms, the nurse obtains a targeted medical history and risk factors for TB. If the patient has one or more medical history or risk factors for TB, the patient is immediately placed on Respiratory Isolation Level 3 (Particulate Respirator), and a diagnostic evaluation is begun. See Appendix F for further details.

Patients are given surgical masks to wear and are instructed to keep their masks on, and are given tissues and instructed to cover their mouths and noses with the tissues when coughing or sneezing. Patients are immediately escorted to a special isolation room. Special clinic rooms with negative airflow and inpatient isolation rooms are available for immediate isolation (see Appendix C: Rooms with Special Engineering Controls for TB Infection Control). The memo “Resource Utilization of Negative Flow Clinic Rooms ” in Appendix C details the procedure to access the clinic rooms. Further details are included in “Guidelines for the Identification, Diagnosis and Initial Treatment of Patients With Tuberculosis” in Appendix G. Samples of patient education materials are included in Appendix H: Patient TB/Respiratory Isolation Education Materials.

TB precautions (AFB Isolation) are used for patients who are known to have active TB and who have not completed therapy until a determination has been made that they are noninfectious. Patients with known or suspected TB who are scheduled for an outpatient visit whenever possible have

appointments scheduled to avoid exposing HIV-infected or otherwise severely immunocompromised persons to TB. (See Guidelines for Management of Tuberculosis Outpatient Visits in Appendix I). Rooms with special engineering controls are available in Diagnostic Radiology, Nuclear Medicine, and other areas for use with TB patients. (See Appendix C). For cough-inducing procedures, negative pressure enclosed booths are available in Respiratory Therapy (see Appendix C for location). For further details, see Section VIII, Cough-Inducing and Aerosol-Generating Procedures.

E. Managing Inpatients Who Have Confirmed or Suspected TB

1. Initiation of Isolation for TB

a. General Guidelines

Any patient suspected of having or known to have infectious TB is placed in a TB isolation room with special ventilation characteristics. Details regarding the indications for isolation are in "Guidelines for the Identification, Diagnosis, and Initial Treatment of Patients with Tuberculosis" in Appendix G. The procedures to admit TB patients and initiate isolation are in "Guidelines for Management of Tuberculosis Inpatient Admissions: Patients With Known or Suspected Pulmonary or Laryngeal Tuberculosis" in Appendix E. Specifically, the patient is placed in a TB isolation room, and placed on AFB Isolation. The patient's health care worker (e.g., the patient's case manager, clinic nurse, physician, research nurse or study coordinator) will contact the HES; the assigned infection control specialist in HES will ensure the patient is placed on AFB Isolation and that workers in other CC areas who may work with the patient or patient specimens are informed. Patients are restricted to the isolation room unless it is absolutely essential that they leave for procedures, or are escorted outside the room by authorized health care workers. If a patient must leave the isolation room, the patient is given a surgical mask to wear and is instructed to keep the mask on, and is given tissues and instructed to cover his/her mouth and nose with the tissues when coughing or sneezing. Escorted patients use back elevators and do not visit common areas of the hospital (e.g., cafeterias, playrooms, waiting areas). Patients are given educational materials explaining the details and rationale of the isolation procedure (See Appendix H).

b. Pediatric Patients

Pediatric patients with suspected or confirmed TB are evaluated for potential infectiousness according to the same criteria as are adults (i.e., symptoms, sputum AFB smears, radiologic findings, and other criteria). Children who may be infectious should be placed in isolation until they are determined to be noninfectious. Pediatric patients who may be infectious include those who have laryngeal or extensive pulmonary involvement, pronounced cough, positive sputum AFB smears, or cavitary TB, or those for whom cough-inducing procedures are performed.

When a child has TB, the source of infection is often a member of the child's family. Therefore, parents and other visitors of all pediatric TB patients should be evaluated for TB as soon as possible. If the evaluation was not performed by the referring physician/ institution, an evaluation can be arranged by contacting the CC Deputy Director for Clinical Care. Until they have been evaluated, or the source case is identified, they should wear surgical masks when in areas of the hospital outside of the child's room, and they should refrain from visiting common areas. (e.g., the cafeteria, lounge areas, or the Children's Inn).

c. Intensive Care Unit Patients

TB patients in ICUs are treated the same as patients in non-critical settings. They are placed in TB isolation and have respiratory secretions submitted for AFB smear and culture if they have undiagnosed pulmonary symptoms suggestive of TB.

d. Readmission of TB Patients

If readmitted, patients who are known to have active TB and who have not completed therapy or have not fulfilled criteria for discontinuation of isolation should be placed in TB isolation until a determination has been made that they are noninfectious.

2. TB Isolation Practices

Patients who are placed in TB isolation are educated about the mechanisms of *M. tuberculosis* transmission and the reasons why they are placed in isolation. They are instructed to cover their mouths and noses with a tissue when coughing or sneezing, even while in the isolation room, to contain infectious organisms before they are expelled into the air. They are also instructed that both doors, the inner anteroom door, and the outer hallway door, must be kept shut at all times. Educational pamphlets are available for patients that explain the details of and reasons for these isolation procedures (See Appendix H).

Efforts are made to facilitate patient adherence to isolation measures (e.g., staying in the TB isolation room). If needed, recreation therapists can conduct activities within the patient's isolation room. Patients in isolation should remain in their isolation rooms with the doors closed. If possible, diagnostic and treatment procedures should be performed in the isolation rooms to avoid transporting patients through other areas of the facility. If patients who may have infectious TB must be transported outside their isolation rooms for medically essential procedures that cannot be performed in the isolation rooms, they should wear closely fitted surgical masks that cover their mouths and noses during transport. Persons transporting the patients do not need respiratory protection unless the patient is unable to wear a surgical mask properly or has MDR-TB. For patients with MDR-TB they should wear respiratory protection (N95 respirator or PAPR) and arrangements should be made for a private elevator; transport personnel should provide the elevator operator with a surgical mask. Procedures for these patients should be scheduled at times when they can be performed rapidly and when waiting areas are less crowded. Further details are available in "Transporting Patients on Isolation" in the *CC Infection Control Program Guidelines* flipchart.

Only rooms which meet the ventilation requirements for isolation rooms should be used for treatment and procedure rooms for the care of patients who have infectious TB or who have an undiagnosed pulmonary disease and are at high risk for active TB. These rooms are identified in Appendix C.

The number of persons entering an isolation room should be minimal. When entering the isolation room, the corridor door should be shut before opening the inner room door. When exiting the isolation room,

the inner door should be shut before opening the outer corridor door. All persons who enter an isolation room should wear respiratory protection. The patient's visitors should be given respirators to wear while in the isolation room, and they should be given general instructions on how to use their respirators. Details regarding which respirators to wear and procedures for training visitors in using particulate respirators are included in Appendix R

Disposable items contaminated with respiratory secretions are not associated with transmission of *M. tuberculosis*. However, for general infection control purposes, these items should be handled and transported in a manner that reduces the risk for transmitting other microorganisms to patients, HCWs, and visitors and that decreases environmental contamination in the health-care facility. Such items should be disposed of in patient waste receptacles or MPW boxes, in accordance with CC policies and procedures.

Equipment used on patients who have TB is usually not involved in the transmission of *M. tuberculosis*, although transmission by contaminated bronchoscopes has been demonstrated. Reusable equipment contaminated with respiratory secretions should be processed according to the CC's "Sterilization and Disinfection" as detailed in the *CC Infection Control Program Guidelines* flipchart.

Although microorganisms are ordinarily found on walls, floors, and other environmental surfaces, these surfaces are rarely associated with transmission of infections to patients or HCWs. This is particularly true with organisms such as *M. tuberculosis*, which generally require inhalation by the host for infection to occur. Therefore, extraordinary attempts to disinfect or sterilize environmental surfaces are not indicated. If a detergent germicide is used for routine cleaning, a hospital-grade, EPA-approved germicide/disinfectant that is not tuberculocidal can be used. The same routine daily cleaning procedures used in other rooms in the facility should be used to clean TB isolation rooms, and personnel should follow isolation practices while cleaning these rooms. For final cleaning of the isolation room after a patient has been discharged, a respirator or PAPR is not necessary if the room has been ventilated for the appropriate amount of time. (See Appendix C to obtain the room's air changes per hour and Table 1 on page 40 to determine the minutes required for 99.9% removal efficiency).

3. Monitoring of Isolation

Procedures used to monitor compliance with isolation procedures have been previously described in Section IV D 5: Observation of TB Infection Control Practices.

4. The TB Isolation Room

TB isolation rooms are single-patient rooms with special ventilation characteristics. The primary purposes of TB isolation rooms are to
a) separate patients who are likely to have infectious TB from other persons;
b) provide an environment that will allow reduction of the concentration of droplet nuclei through various engineering methods; and
c) prevent the escape of droplet nuclei from the TB isolation room and treatment room, thus preventing entry of *M. tuberculosis* into the corridor and other areas of the facility.

To prevent the escape of droplet nuclei the TB isolation rooms are maintained under negative pressure. Doors to isolation rooms should be kept closed, except when patients or personnel must enter or exit the room, so that negative pressure can be maintained. When entering or exiting, one of the anteroom doors (either the inner room door or the outer corridor door) must be closed; both doors should not be open at once. Negative pressure TB isolation rooms in the CC are monitored continuously by airflow monitors, and negative pressure is verified monthly by air balancing assessments. TB isolation rooms in the CC equal or exceed the minimum 6 air changes per hour (ACH) for TB isolation and treatment rooms, as recommended by the CDC.[3] Ventilation rates of > 6 ACH are likely to produce an incrementally greater reduction in the concentration of microorganisms in the room. Where feasible, this airflow rate should be increased to >12 ACH for TB isolation rooms by adjusting or modifying the ventilation system

[3] CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994. MMWR 1994;43(No. RR13):29.

or by using auxiliary means (e.g., recirculation of air through fixed HEPA filtration systems or portable air cleaners).

Air from TB isolation rooms and treatment rooms used to treat patients who have known or suspected infectious TB should preferably be exhausted to the outside. The air should not be recirculated into the general ventilation. In some instances, recirculation of air into the general ventilation system is unavoidable (i.e., in existing facilities in which the ventilation system or facility configuration makes venting the exhaust to the outside impossible). In such cases, HEPA filters are installed in the exhaust duct leading from the room to the general ventilation system to remove infectious organisms and particulates the size of droplet nuclei from the air before it is returned to the general ventilation system. Air from TB isolation and treatment rooms in new or renovated facilities should not be recirculated into the general ventilation system.

Although not required, an anteroom may increase the effectiveness of the isolation room by minimizing the potential escape of droplet nuclei into the corridor when the door is opened. To work effectively, the anteroom should have positive air pressure in relation to the isolation room. The pressure relationship between the anteroom and the corridor may vary according to ventilation design.

Although upper-room air ultraviolet germicidal irradiation (UVGI) may be used as an adjunct to general ventilation in the isolation room, at the current time the CC does not use UVGI.

The CC should have enough isolation rooms to appropriately isolate all patients who have suspected or confirmed active TB. This number is estimated using the results of the risk assessment of the health-care facility. Grouping isolation rooms together in one area of the CC may reduce the possibility of transmitting *M. tuberculosis* to other patients and may facilitate care of TB patients and the installation and maintenance of optimal engineering (particularly ventilation) controls.

5. Management of Patients Who Do Not Adhere to Isolation Practices

The CC is not a primary care hospital, but a medical research hospital. The most important person in medical research is the patient, who has

voluntarily consented to participate in a research protocol. Nonetheless, if a CC patient with suspected or confirmed active TB does not adhere to isolation practices, these actions can place other patients, HCWs, and visitors at risk for becoming infected with TB. Thus, a management strategy is necessary to deal with noncompliant patients.

If a patient does not adhere to the recommended isolation practices (e.g., staying in the TB isolation room), the first intervention is to review with the patient the importance and necessity of these practices to protect the health of others. Consults from the Social Work Department and the CC Patient Representative may be beneficial. If the patient persists in not complying, a formal conference with the patient is indicated. Participants should include the patient, the patient's primary nurse, primary physician and/or senior attending physician, a representative from CC Bioethics, and other appropriate individuals (e.g., next of kin, guardian, Infectious Disease Specialist physician). The purpose of the conference, which should be documented in the medical record, is:

(1) to formally review the importance and necessity of the isolation practices;

(2) to review the patient's responsibilities, as outlined in the CC Medical Staff Handbook. Specifically the responsibility to comply with his/her protocol, to cooperate with hospital staff, to ask questions if directions or procedures are not clear, and to follow NIH rules and regulations affecting patient care and treatment;

(3) to explain the consequences if the patient continues to be noncompliant with the recommended isolation practices. Specifically, in order to protect other patients and staff, as a last resort the patient may have to be discharged from the CC. When the patient leaves the CC, arrangements will be made to escort him/her from the NIH reservation in isolation and the Montgomery County Health Department as well as the patient's local health department will be notified. If the patient lives locally in Montgomery County or leaves the CC against medical advice, Montgomery County regulations will go into effect. If the patient is infectious and presents a risk to the community, Montgomery County has the power to obtain a court order and have the patient arrested and placed in isolation in a hospital jail;

(4) to ensure that the patient understands the seriousness and importance of complying with isolation practices it may be beneficial

to have the patient sign a "contract" stating that he/she understands the importance of complying with the isolation practices, has had the consequences of noncompliance explained, and agrees to comply with the isolation practices.

If the patient still persists in not complying with recommended isolation practices, the primary nurse and/or primary physician should contact the Hospital Epidemiology Service as soon as possible. A meeting should be convened to decide the best approach on a case-by-case basis. Meeting participants should include the primary nurse and physician, the senior attending physician, the infection control specialist, an Infectious Disease Specialist physician, a representative from CC bioethics, and CC legal counsel. Participants will determine the level of risk the patient's noncompliance presents to others, and if there are other options to explore in order to obtain compliance. Factors to be considered include the infectivity of the patient, the sensitivity of the organism to antitubercular drugs, and the patient's behavioral status and social support network (See Appendix J, Determining the Infectiousness of a TB Patient). If the patient's noncompliance is felt to present a risk to other patients, visitors, or staff, then the meeting participants should consider discharging the patient and the discharge plan should be coordinated (see Discharge Planning below). The referring physician should be notified, as well as the Montgomery County Health Department and the patient's local health department (see Appendix K, Protocols for Coordination With the Public Health Department). Arrangements should be made to ensure the patient is escorted safely from the CC.

6. Discontinuation of TB Isolation

The decision to discontinue TB isolation is made on a case-by-case basis in consultation with the patient's primary physician, the infection control specialist, and the Infectious Disease Specialist physician. The following guidelines are applicable:

a. Discontinuing TB Isolation for Suspected Active TB

General Situation:

For patients who are placed on TB isolation because of suspected pulmonary TB (positive skin-test results or symptoms suggestive of TB), isolation may generally be discontinued if the chest radiograph is

normal. Radiographic abnormalities that strongly suggest active TB include upper lobe infiltration, particularly if cavitation is seen, and patchy or nodular infiltrates in the apical or subapical posterior upper lobes or the superior segment of the lower lobe. However, if the patient is HIV-infected, radiographic presentation may be unusual. HIV-infected patients less commonly exhibit typical apical cavitary disease. They may have infiltrates in any lung zone, often associated with mediastinal and/or hilar adenopathy, or they may rarely have a normal chest radiograph.

Exceptions:

Patients on TB isolation for suspected active TB may need additional testing before isolation can be discontinued in the following situations:

- HIV-infected patients with suspected active TB should remain on TB isolation until they have had either three consecutive negative sputum smears (concentrated) collected on different days or a negative bronchial lavage evaluation (including negative BAL fluid smears and negative post-bronchoscopy sputum examination).

- Patients who have (1) either a history of known TB exposure, a history of TB infection not successfully treated, or a history of a positive PPD skin-test, and (2) any infiltrate or adenopathy on chest radiograph, should remain on TB isolation until they have had either three consecutive negative sputum smears (concentrated) collected on different days or a negative bronchial lavage evaluation (including negative BAL fluid smears and negative post-bronchoscopy sputum examination).

b. Discontinuing TB Isolation for Confirmed Active TB Not Known to be MDR-TB

Patients with confirmed active TB that is not known to be MDR-TB should remain in TB isolation while hospitalized until they have received appropriate treatment, clinical improvement is noted (i.e., reduction in cough, resolution of fever), and they have had either three consecutive negative sputum smears (concentrated) collected on different days or a negative bronchial lavage evaluation (including negative BAL fluid smears and negative post-bronchoscopy sputum examination). Individuals not meeting these criteria will be evaluated

on a case-by-case basis. A patient whose condition deteriorates will need to be re-evaluated and may need isolation reinstituted.

c. Step-Down Discontinuation of TB Isolation for Patients with MDR-TB

Patients who have been treated for MDR-TB have their TB isolation discontinued in a step-down fashion. Patients must have received appropriate treatment, clinical improvement is noted (i.e., reduction in cough, resolution of fever), and they must have had either three consecutive negative sputum smears (concentrated) collected on different days or a negative bronchial lavage evaluation (including negative BAL fluid smears and negative post-bronchoscopy sputum examination). At this time step-down discontinuation of TB isolation may begin:

(1) AFB Isolation is discontinued; maintain strict adherence to Universal Precautions.
(2) The patient may remain in a negative pressure isolation room until transferred to a private room.
(3) In general, respiratory barrier equipment is to be used only as indicated per Universal Precautions. However, in situations in which aerosol-generating procedures are performed, then tuberculosis respiratory barrier equipment (PAPR or N95 respirator) should be utilized. HES should be notified in anticipation of these procedures to make necessary arrangements with the departments involved.
(4) If the patient is compliant, the patient may roam the CC with these instructions: the patient should use the back elevators, should not visit the cafeteria during high-traffic periods, should not socialize with patients, must demonstrate strict adherence at all times to nursing staff instructions, and must demonstrate compliance at all times to CC guidelines for patients.
(5) No special restrictions for visitors.
(6) In the event that the patient's condition deteriorates, the patient will be re-evaluated immediately and may need isolation reinstituted.

7. Discharge Planning

Before a TB patient is discharged, CC staff and public health authorities should collaborate to ensure continuation of therapy. Discharge planning should include, at a minimum:

(a) a confirmed outpatient appointment with the provider who will manage the patient until the patient is cured;
(b) sufficient medication to take until the outpatient appointment; and
(c) placement into case management (e.g., DOT) or outreach programs of the public health department.

These plans should be initiated and in place before the patient's discharge. See the DIRECTORY ASSISTANCE section at the front of the TB Control Plan for contacts and phone numbers of the local health departments.

Patients who may be infectious at the time of discharge should only be discharged to facilities that have isolation capability or to their homes. Plans for discharging a patient who will return home must consider whether all the household members were infected previously and whether any uninfected household members are at very high risk for active TB if infected (e.g., children <4 years of age or persons infected with HIV or otherwise severely immunocompromised). If the household does include such persons, arrangements should be made to prevent them from being exposed to the TB patient until a determination has been made that the patient is noninfectious.

VI. ENGINEERING CONTROLS

Engineering controls for TB include: (a) local exhaust ventilation (i.e., source control), (b) general ventilation, and (c) air cleaning. General ventilation considerations include (a) dilution and removal of contaminants, (b) airflow patterns within rooms, (c) airflow direction in the CC, (d) negative pressure in rooms, and (e) TB isolation rooms. Air cleaning or disinfection can be accomplished by filtration of air (e.g., through HEPA filters) or by UVGI. Details regarding ventilation design, evaluation, and supplemental approaches are described in Supplement 3 of the CDC guidelines (Appendix A), which were used to guide our design and implementation of engineering controls.

A. General Ventilation

The CC has available considerable expertise in ventilation engineering in a hospital setting. Resources include the CC Office of Facility Management Manager and CC Environmental Safety Officer, as well as engineers in CC Maintenance and Engineering and ventilation

contractors hired through the NIH Division of Engineering. In particular, the Office of Facility Management Manager and Environmental Safety Officer work closely with the Hospital Epidemiology Service to assist in controlling airborne infections.

Ventilation in the CC meets applicable federal, state, and local requirements. The direction of airflow in the CC is designed, constructed, and maintained so that air flows from clean areas to less-clean areas.

With the exception of patients enrolled in MDR-TB research protocols, there is not a high prevalence of TB among CC patients. Therefore, the CC does not supplement the general ventilation or use additional engineering approaches in general-use areas such as waiting-room areas. Patients enrolled in MDR-TB protocols are known to be infected before coming to the CC and do not visit general-use areas. They are escorted, wearing a surgical mask, directly to specially ventilated TB isolation rooms.

B. Additional Engineering Control Approaches

1. HEPA Filtration

HEPA filters are used in selected locations in the CC to reduce or eliminate infectious droplet nuclei from room air or exhaust. These methods include placement of HEPA filters in exhaust ducts discharging air from booths or enclosures into the surrounding room and HEPA filters in exhaust ducts discharging air from certain diagnostic/treatment rooms into the general ventilation system. These rooms are identified in Appendix C.

2. UVGI

UVGI is currently not used in the CC as air disinfection for TB control.

C. Schedule for the Inspection, Maintenance, and Performance Monitoring of Engineering Controls

A multidisciplinary group (Hospital Epidemiology Service, CC Office

of Facility Management, CC Environmental Safety Officer, and representatives from the CC Maintenance Unit (CCMU) and the NIH Office of Research Services Division of Engineering Services [OD ORS DES]) was convened to ensure that the CC has a program in place to inspect, maintain, and monitor the engineering controls used in the CC. These engineering controls currently include negative pressure rooms used for TB isolation, and HEPA filter units. A list of the rooms that have special ventilation and/or HEPA filters for TB control is included in Appendix C. Although technically considered respiratory protective devices, the CC PAPRs are also included in this section because they are scheduled for routine inspection and maintenance.

The negative pressure rooms used for patient care (i.e., TB isolation rooms), and most of the negative pressure procedure and treatment rooms are equipped with continuous pressure monitoring devices. Preventive maintenance and inspection of CC air handling equipment for these rooms is provided by the CC Maintenance Unit of DES. Inspection and maintenance is performed annually; records are kept in the CCMU office. To ensure that the continuous monitoring devices are operating properly, the negative pressure is verified routinely by the DES ventilation contractor (currently Precision Balancing, Inc.), who inspects and monitors the air balancing. A copy of the inspection, maintenance, and monitoring procedures are included in Appendix L. Standard operating procedures for maintenance personnel responding to air pressure monitoring alarms or trouble calls from nursing staff have been developed; a copy is included in Appendix L. Routine air balancing reports are submitted to the Office of Facility Management, the CC Environmental Safety Officer and the HES; reports are on file in the HES office.

The HEPA filters in the CC are inspected and maintained by an outside contractor through the NIH Division of Safety, Occupational Safety and Health Branch (DS OSHB). These procedures, which include a quantitative leakage and filter performance test, are performed at least annually. A copy of the regularly scheduled maintenance program to monitor the HEPA filters is also included in Appendix L. Reports are available to HES and the CC Environmental Safety Officer. The reports are on file in the NIH Division of Safety Office.

The PAPRs used in the CC for TB control are also scheduled for routine inspection and maintenance. The CC Biomedical Engineering Section replaces the rechargeable batteries according to policy and performs an air-flow test to ensure that the devices work properly. The HEPA filters are replaced annually and when units are returned to Central Hospital Supply for decontamination. A copy of the regularly scheduled inspection and maintenance procedures are included in Appendix L. Reports are submitted to the HES and are on file in the HES Office.

VII. RESPIRATORY PROTECTION

Personal respiratory protection is used by:

- persons entering rooms in which patients with known or suspected infectious TB are being isolated;
- persons present during cough-inducing or aerosol-generating procedures performed on such patients; and
- persons in other settings where administrative and engineering controls are not likely to protect them from inhaling infectious airborne droplet nuclei. These settings include transporting patients who may have infectious TB in emergency transport vehicles and providing urgent surgical or dental care to patients who may have infectious TB before a determination has been made that the patient is noninfectious.

A. Performance Criteria for Personal Respirators for Protection Against Transmission of *M. tuberculosis*

Respiratory protective devices used by CC staff for protection against *M. tuberculosis* meet the National Institute of Occupational Safety and Health (NIOSH) revised testing and certification procedures, contained in 42 CFR 84, published in the June 8, 1995 *Federal Register* (60 FR 110:30336). This rule replaces the outdated Department of Labor/Mine Safety and Health Administration (MSHA) certification requirements for respiratory protective devices. Specifically, respirators meet the following standard performance criteria:

1. The ability to filter particles 1 µm in size in the unloaded state with a filter efficiency of ≥95% (i.e., filter leakage of ≤5%), given flow rates of up to 50L per minute.

2. The ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of ≤10%.
3. The ability to fit the different facial sizes and characteristics of HCWs, which can usually be met by making the respirators available in at least three sizes.
4. The ability to be checked for facepiece fit, in accordance with standards established by OSHA and good industrial hygiene practice, by HCWs each time they put on their respirators.

The filter efficiency tests apply to filters for non-powered respirators. The particulate respirators used at the CC meet the NIOSH filter designation for class N95.

In some settings, HCWs may be at risk for two types of exposure: (a) inhalation of *M. tuberculosis* and (b) mucous membrane exposure to fluids that may contain bloodborne pathogens. In these settings, protection against both types of exposure should be used.

When operative procedures (or other procedures requiring a sterile field) are performed on patients who may have infectious TB, respiratory protection worn by the HCW should serve two functions: (a) it should protect the surgical field from the respiratory secretions of the HCW and (b) it should protect the HCW from infectious droplet nuclei that may be expelled by the patient or generated by the procedure. Respirators with expiration valves and positive-pressure respirators do not protect the sterile field. See section XIII.A for further details regarding respirators in operative procedures.

B. Specific Respirators

Only NIOSH-approved respirators are used in the CC. The current standard level of respiratory protection for TB control compatible with patient-care delivery in the CC is NIOSH class N95 particulate respirators. The CC Standardization Committee evaluated several candidate N95 respirators and selected the Affinity™ PRO-N95 and the Affinity™ PLUS-N95. Maintenance Free Respirator. For HCWs who are bearded or otherwise cannot obtain an adequate fit, or who must spend long periods of time in the patient isolation room, powered air-purifying particulate respirators (PAPRs) are used. The PAPR products used in the CC are manufactured by 3M Air-Mate® HEPA 10 (hood/cape) and Air-Mate® HEPA 12 (head cover).The PAPR is the required respirator for Special Respiratory Isolation Precautions.

C. Personal Respiratory Protection Program

The CC has a personal respiratory protection program for HCWs who need to use respirators for protection against infection with *M. tuberculosis*. Because administrative measures are used to limit the number of HCWs who enter TB isolation rooms or areas, there are a limited number of HCWs who need to be included in the respiratory protection program.

1. Assignment of Responsibility

Supervisory responsibility for the respiratory protection program is assigned to the CC Environmental Safety Officer.

2. Written Operating Procedures

Written standard operating procedures that contain information concerning all aspects of the respiratory protection program are included in Appendix M.

3. Medical Screening

HCWs are not assigned to a task requiring use of respirators unless they are physically able to perform the task while wearing the respirator. HCWs are screened at the time of their initial training session. The screening process begins with a questionnaire for pertinent medical conditions, and the results of the screening are used to identify HCWs who need further evaluation by OMS. The screening questionnaire is included in Appendix M.

Few medical conditions preclude the use of most negative-pressure particulate respirators. HCWs who have mild pulmonary or cardiac conditions may report discomfort with breathing when wearing negative-pressure particulate respirators, but these respirators are unlikely to have adverse health effects on the HCWs. HCWs with more severe cardiac or pulmonary conditions may have difficulty performing duties while wearing negative-pressure respirators, and may even be unable to use some PAPRs because of the added weight of these respirators.

4. Training

HCWs who wear respirators and the persons who supervise them are informed about the necessity for wearing respirators and the potential risks associated with not doing so. The respirator training includes:

- Information about the nature, extent, and specific hazards of *M. tuberculosis* transmission in the CC.
- A description of specific risks for TB infection among persons exposed to *M. tuberculosis*, of any subsequent treatment with INH or other chemoprophylactic agents, and of the possibility of active TB disease.
- A description of engineering controls and work practices and the reasons why they do not eliminate the need for personal respiratory protection.
- An explanation for selecting a particular type of respirator, how the respirator is maintained and stored, and the operation, capabilities, and limitations of the respirator provided.
- Instruction in how the HCW wearing the respirator should inspect, put on, fit check, and correctly wear the provided respirator (i.e., achieve and maintain proper face-seal fit on the HCW's face).
- An opportunity to handle the provided respirator and learn how to put it on, wear it properly, and check the important parts.
- Instruction in how to recognize an inadequately functioning respirator.

5. Face-Seal Fit Testing and Fit Checking

HCWs undergo fit testing to identify a respirator that adequately fits each individual HCW. The HCW receives fitting instructions that include demonstrations and practice in how the respirator should be worn, how it should be adjusted, and how to determine if it fits properly. The HCW is taught to check the fit before each use.

6. Respirator Inspection, Cleaning, Maintenance, and Storage

Respirator maintenance is important and applies to both respirators with replaceable filters (PAPRs) and particulate respirators that are classified

as disposable but that are reused. Manufacturer's instructions for inspecting, cleaning, and maintaining respirators are followed to ensure that the respirator continues to function properly.

7. Periodic Evaluation of the Personal Respiratory Protection Program

The Personal Respiratory Protection Program is evaluated at least once a year, and both the written operating procedures and program administration are revised as necessary based on the results of the evaluation. Elements of the program that are evaluated include work practices and employee acceptance of respirator use (i.e., subjective comments made by employees concerning comfort during use and interference with duties).

VIII. COUGH-INDUCING AND AEROSOL-GENERATING PROCEDURES

A. General Guidelines

Procedures that involve instrumentation of the lower respiratory tract or induce coughing can increase the likelihood of droplet nuclei being expelled into the air. These cough-inducing procedures include endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments (e.g., pentamidine therapy), pulmonary function testing, and bronchoscopy. Other procedures that can generate aerosols (e.g., irrigation of tuberculous abscesses, homogenizing or lyophilizing tissue, or other processing of tissue that may contain tubercle bacilli) are also covered by these recommendations.

- Cough-inducing procedures should not be performed on patients who may have infectious TB unless the procedures are absolutely necessary and can be performed with appropriate precautions.

- All cough-inducing procedures performed on patients who may have infectious TB should be performed using local exhaust ventilation devices (e.g., booths or special enclosures) or, if this is not feasible, in a room that meets the ventilation requirements for TB isolation.

- HCWs should wear respiratory protection when present in rooms or enclosures in which cough-inducing procedures are being performed on patients who may have infectious TB.

- After completion of cough-inducing procedures, patients who may have infectious TB should remain in their isolation rooms or enclosures and not return to common waiting areas until coughing subsides. They should be given tissues and instructed to cover their mouths and noses with the tissues when coughing. If TB patients must recover from sedatives or anesthesia after a procedure (e.g., after a bronchoscopy), they should be placed in separate isolation rooms (and not in recovery rooms with other patients) while they are being monitored.

- Before the booth, enclosure, or room is used for another patient, enough time should be allowed to pass for at least 99.9% of airborne contaminants to be removed. This time will vary according to the efficiency of the ventilation or filtration used, according to Table 1 (from the CDC 1994 guidelines). (See Appendix C to obtain the room's air changes per hour or contact the HES for the most recent data).

Table 1. Air Changes per Hour (ACH) and Time in Minutes Required for Removal Efficiencies of 90%, 99%, and 99.9% of Airborne Contaminants*

	Minutes Required for a Removal Efficiency of:		
ACH	90%	99%	99.9%
1	138	276	414
2	69	138	207
3	46	92	138
4	35	69	104
5	28	55	83
6	23	46	69
7	20	39	59
8	17	35	52
9	15	31	46
10	14	28	41
11	13	25	38
12	12	23	35
13	11	21	32
14	10	20	30
15	9	18	28
16	9	17	26
17	8	16	24
18	8	15	23
19	7	15	22
20	7	14	21
25	6	11	17
30	5	9	14
35	4	8	12
40	3	7	10
45	3	6	9
50	3	6	8

* This table has been adapted from the formula for the rate of purging airborne contaminants. Values have been derived from the formula $t_1 = [\ln (C_2 + C_1) + (Q + V)] \times 60$, with $T_1 = 0$ and $C_2 + C_1 -$ (removal efficiency + 100), and where:

t_1 = initial timepoint
C_1 = initial concentration of contaminant
Q = air flow rate (cubic feet per hour)
V = room volume (cubic feet)
Q + V = ACH

The times given assume perfect mixing of the air within the space (i.e., mixing factor = 1). However, perfect mixing usually does not occur, and the mixing factor could be as high as 10 if air distribution is very poor. The required time is derived by multiplying the appropriate time from the table by the mixing factor that has been determined for the booth or room. The factor and required time should be included in the operating

instructions provided by the manufacturer of the booth or enclosure, and these instructions should be followed.

B. Special Considerations for Bronchoscopy

- If performing bronchoscopy in positive-pressure rooms (e.g., operating rooms) is unavoidable, TB should be ruled out as a diagnosis before the procedure is performed. If the bronchoscopy is being performed for the purpose of diagnosing pulmonary disease and that diagnosis could include TB, the procedure should be performed in a room that meets TB isolation ventilation requirements.

C. Special Considerations for the Administration of Aerosolized Pentamidine

- Patients should be screened for active TB before prophylactic therapy with aerosolized pentamidine is initiated. Screening should include obtaining a medical history and performing skin testing and chest radiography.

- Before each subsequent treatment with aerosolized pentamidine, patients should be screened for symptoms suggestive of TB (e.g., development of a productive cough). If such symptoms are elicited, a diagnostic evaluation for TB should be initiated.

- Patients who have suspected or confirmed active TB should take, if clinically practical, oral prophylaxis for *P. carinii* pneumonia.

IX. EDUCATION AND TRAINING OF HCWs

All HCWs, including credentialed physicians, receive education regarding TB. The infection control orientation for all new employees, regardless of whether or not they will have occupational exposure to TB, includes basic information about TB and is conducted before initial assignment. This training includes information on how TB is transmitted, isolation for TB patients, the special respirators required, and the requirement that HCWs with occupational exposure receive annual PPD testing or evaluations.

More detailed education and training is provided to employees with occupational exposure to TB, and is included with annual Universal Precautions training. This annual training includes the following elements:

- The basic concepts of *M. tuberculosis* transmission, pathogenesis, and diagnosis, including information concerning the difference between latent TB infection and active TB disease, and the signs and symptoms of TB.

- The potential for occupational exposure to persons who have infectious TB in the CC, the ability of the CC to properly isolate the patients who have active TB, and situations with increased risk for exposure to *M. tuberculosis*.

- The principles and practices of infection control that reduce the risk for transmission of *M. tuberculosis*, including information concerning the hierarchy of TB infection-control measures.

- The purpose of PPD skin testing, the significance of a positive PPD test result, and the importance of participating in the skin-test program.

- The principles of preventive therapy for latent TB infection.

- The HCW's responsibility to seek prompt medical evaluation if a PPD test conversion occurs or if symptoms develop that could be caused by TB. Medical evaluation will enable HCWs who have TB to receive appropriate therapy and will help to prevent transmission of *M. tuberculosis* to patients and other HCWs.

- The principles of drug therapy for active TB.

- The importance of notifying OMS or HES if the HCW is diagnosed with active TB.

- The higher risks associated with TB infection in persons who have HIV infection or other causes of severely impaired cell-mediated immunity, including the more frequent and rapid development of clinical TB after infection with *M. tuberculosis*, and the high mortality rate associated with MDR-TB in such persons.

- The potential development of cutaneous anergy as immune function (as measured by CD4+ T-lymphocyte counts) declines.

- The principles of PPD screening among BCG recipients.

Examples of the educational handouts and test materials are included in Appendix N.

X. HCW COUNSELING, SCREENING, AND EVALUATION

The CC has a TB counseling, screening, and prevention program for HCWs to protect both HCWs and patients. HCWs who have positive PPD test results, PPD test conversions, or symptoms suggestive of TB are identified, evaluated to rule out a diagnosis of active TB, and started on therapy or preventive therapy if indicated. In addition, the results of the HCW PPD screening program contribute to evaluation of the effectiveness of current infection-control practices.

A. Counseling HCWs Regarding TB

- Because of the increased risk for rapid progression from latent TB infection to active TB in HIV-infected or otherwise severely immunocompromised persons, all HCWs should know if they have a medical condition or are receiving a medical treatment that may lead to severely impaired cell-mediated immunity. HCWs who may be at risk for HIV infection should know their HIV status (i.e., they are encouraged to voluntarily seek counseling and testing for HIV antibody status). NIH HCWs with potential occupational exposure to blood or other potentially infectious materials are eligible for and encouraged to enroll in the OMS's Retroviral Exposure Surveillance Program (RESP), which provides this testing confidentially and free of charge. In addition, during annual TB training, HCWs who think they may be immunocompromised are encouraged to obtain a confidential evaluation from OMS. Knowledge of these conditions allows the HCW to seek the appropriate preventive measures and to consider voluntary work reassignments. Of particular importance is that HCWs need to know their HIV status if they are at risk for HIV infection and they work in settings where patients who have MDR-TB may be encountered.

- All HCWs are informed about the need to follow existing recommendations for infection control to minimize the risk for exposure to infectious agents; implementation of these recommendations will greatly reduce the risk for occupational infections among HCWs. HCWs are also informed about the potential risks to severely immunocompromised persons associated with caring for patients who have some infectious diseases, including TB. Limiting exposure to TB patients is the most protective measure that severely immunosuppressed HCWs can take to avoid becoming infected with *M. tuberculosis*.

- The CC will make reasonable accommodations (e.g., alternative job assignments) for employees who have a health condition that compromises cell-mediated immunity and who work in settings where they may be exposed to *M. tuberculosis*. Evaluation of these situations also includes consideration of the provisions of the Rehabilitation Act of 1973, the Americans With Disabilities Act of 1990 and other applicable federal, state, and local laws.

- HCWs who are known to be HIV-infected or otherwise severely immunosuppressed should be tested for cutaneous anergy at the time of PPD testing.

- Information provided by HCWs regarding their immune status is treated confidentially. If the HCW requests voluntary job reassignment, the confidentiality of the HCW is maintained.

B. Screening HCWs for Active TB

Any HCW who has a persistent cough (i.e., a cough lasting ≥3 weeks), especially in the presence of other signs or symptoms compatible with active TB (e.g., weight loss, night sweats, bloody sputum, anorexia, or fever), should be evaluated promptly for TB. The HCW should not return to the workplace until a diagnosis of TB has been excluded or until the HCW is on therapy and a determination has been made that the HCW is noninfectious. Further details may be found in OMS's Tuberculosis Surveillance Program procedures in Appendix O.

C. Screening HCWs for Latent TB Infection

- The CC's TB risk assessment identifies which HCWs have potential for exposure to *M. tuberculosis*. The criteria to identify HCWs with potential for exposure to *M. tuberculosis* is defined in Section III of this TB Control Plan. These HCWs must be included in a periodic PPD testing program. The procedures described in OMS's Tuberculosis Surveillance Program in Appendix O determine the frequency with which TB exposure may occur to HCWs and thus the baseline frequency with which the HCWs should be tested. Periodic risk assessments may indicate more frequent and/or less frequent periodic PPD testing.

- The CC strives to ensure that physicians and other personnel not paid by, but working in, the CC receive skin testing at appropriate intervals for

their occupational group and work location. This is accomplished by several mechanisms: (1) “Boilerplate” language was developed, to be included in contracts, to assist contractors in complying with applicable federal and state regulations regarding the control of infectious diseases in health-care facilities. This language was distributed to CC contractors through the Director, Office of Procurement Management, in March, 1996 (see Appendix P). (2) The CC requires that all health-care workers credentialed for patient care obtain annual PPD testing (or evaluation for clinical disease if PPD-positive). For consultants, who are not NIH employees, OMS will also provide individual physician consultants PPD testing if requested.

- During the pre-employment physical or when applying for hospital privileges, the HCWs who have potential for exposure to *M. tuberculosis*, including those with a history of BCG vaccination, have baseline PPD skin testing performed. For HCWs who have not had a documented negative PPD test result during the preceding 12 months, the baseline PPD testing should employ the two-step method; this will detect boosting phenomena that might be misinterpreted as a skin-test conversion.

- HCWs who have a documented history of a positive PPD test, adequate treatment for disease, or adequate preventive therapy for infection, are exempt from further PPD screening unless they develop signs or symptoms suggestive of TB.

- PPD-negative HCWs undergo repeat PPD testing at regular intervals as determined by the risk assessment. In addition, these HCWs are tested whenever they have been exposed to a TB patient and appropriate precautions were not observed at the time of exposure.

- All PPD tests are administered, read, and interpreted in accordance with current guidelines by specified trained personnel in OMS. At the time their test results are read, HCWs are informed about the interpretation of both positive and negative PPD test results. This information indicates that the interpretation of an induration that is 5–9 mm in diameter depends on the HCW’s immune status and history of exposure to persons who have infectious TB. Specifically, HCWs who have indurations of 5–9 mm in diameter are advised that such results may be considered positive for HCWs who are contacts of persons with infectious TB or who have HIV infection or other causes of severe immunosuppression (e.g., immunosuppressive therapy for organ transplantation.)

- When an HCW who is not assigned regularly to a single work area has a PPD test conversion, appropriate personnel identify the areas where the HCW worked during the time when infection was likely to have occurred. This information is then considered in analyzing the risk for transmission in those areas.

- In any area of the facility where transmission of *M. tuberculosis* is known to have occurred, a problem evaluation should be conducted, (See Section XI. PROBLEM EVALUATION) and the frequency of skin testing should be determined according to the applicable risk category.

- PPD test results are recorded confidentially in the individual HCW's employee health record and in an aggregate database of all HCW PPD test results. The database is analyzed periodically to estimate the risk for acquiring new infection in specific areas or occupational groups in the CC. As part of the CC periodic risk assessment, OMS routinely provides the HES with semi-annual reports: the April–September report is generated in October and the October–March report is generated in April of each year. Upon request by HES, OMS will provide other analyses as needed.

D. Evaluation and Management of HCWs Who Have Positive PPD Test Results or Active TB

Further details for this section are available in Appendix O: OMS Tuberculosis Surveillance Program.

1. Evaluation

- All HCWs with newly recognized positive PPD test results or PPD test conversions are evaluated promptly for active TB. This evaluation includes a clinical examination and a chest radiograph. If the history, clinical examination, or chest radiograph is compatible with active TB, additional tests are performed (see Section V.B.). If symptoms compatible with TB are present, the HCW is excluded from the workplace until either (a) a diagnosis of active TB is ruled out or (b) a diagnosis of active TB was established, the HCW is being treated, and a determination has been made that the HCW is noninfectious. HCWs who do not have active TB are evaluated for preventive therapy according to published guidelines.

- If an HCW's PPD test result converts to positive, a history of confirmed or suspected TB exposure is obtained in an attempt to determine the potential source (see "PPD Conversion Assessment" in Appendix O). When the source of exposure is known, every effort is made to identify the drug-susceptibility pattern of the *M. tuberculosis* isolated from the source so that the correct curative or preventive therapy can be initiated for the HCW with the PPD test conversion. The drug-susceptibility pattern is recorded in the HCW's medical record, where it will be available if the HCW subsequently develops active TB and needs therapy specific for the drug-susceptibility pattern.

- All HCWs, including those with histories of positive PPD test results, are reminded periodically about the symptoms of TB and the need for prompt evaluation of any pulmonary symptoms suggestive of TB.

2. Routine and Follow-Up Chest Radiographs

- Routine chest radiographs are not required for asymptomatic, PPD-negative HCWs. HCWs with positive PPD test results should have a chest radiograph as part of the initial evaluation of their PPD test; if negative, repeat chest radiographs are not needed unless symptoms develop that could be attributed to TB. Further details of follow-up of HCWs with PPD conversions are included in Appendix O.

3. Workplace Restrictions

a. Active TB

- HCWs with pulmonary or laryngeal TB pose a risk to patients and other HCWs while they are infectious, and they are excluded from the workplace until they are noninfectious. The same work restrictions apply to all HCWs regardless of their immune status.

- Before the HCW who has active TB can return to the workplace, the HCW must be medically cleared by OMS. Medical clearance is provided only after the HCW completes at least two weeks of therapy and has three consecutive negative

sputum smears collected on different days. The subsequent clinical course and compliance with treatment is closely monitored by the OMS TB Surveillance Program nurse.

- HCWs with active laryngeal or pulmonary TB who discontinue treatment before they are cured are evaluated promptly for infectiousness. If the evaluation determines that they are still infectious, they are excluded from the workplace until treatment has been resumed, an adequate response to therapy has been documented, and three more consecutive sputum AFB smears collected on different days have been negative.

- HCWs who have TB at sites other than the lung or larynx usually do not need to be excluded from the workplace if a diagnosis of concurrent pulmonary TB has been ruled out.

b. Latent TB Infection

- HCWs receiving preventive treatment for latent TB infection are not restricted from their usual work activities.

- HCWs with latent TB infection who cannot take or who do not accept or complete a full course of preventive therapy are not excluded from the workplace. These HCWs are counseled about the risk for developing active TB and instructed regularly to seek prompt evaluation if signs or symptoms develop that could be caused by TB.

XI. PROBLEM EVALUATION

Epidemiologic investigations may be indicated for several situations. These include, but are not limited to: (a) the occurrence of PPD test conversions or active TB in HCWs; (b) the occurrence of possible person-to-person transmission of *M. tuberculosis*; and (c) situations in which patients or HCWs with active TB are not promptly identified and isolated, thus exposing other persons in the facility to *M. tuberculosis*. The general objectives of the epidemiologic investigations in these situations are as follows:

1) to determine the likelihood that transmission of and infection with *M. tuberculosis* has occurred in the CC;

2) to determine the extent to which *M. tuberculosis* has been transmitted;

3) to identify those persons who have been exposed and infected, enabling them to receive appropriate clinical management;

4) to identify factors that could have contributed to transmission and infection and to implement appropriate interventions; and

5) to evaluate the effectiveness of any interventions that are implemented and to ensure that exposure to and transmission of *M. tuberculosis* have been terminated.

The exact circumstances of these situations are likely to vary considerably, and the associated epidemiologic investigations are tailored to the individual circumstances. The following sections provide general guidance for conducting these investigations, which are further detailed in Appendix Q.

A. Investigating PPD Test Conversions and Active TB in HCWs

1. Investigating PPD Test Conversions in HCWs

PPD test conversions may be detected in HCWs as a result of a contact investigation, in which case the probable source of exposure and transmission is already known (see Section XI.C below), or as a result of routine screening, in which case the probable source of exposure and infection is not already known and may not be immediately apparent.

If a skin-test conversion in a HCW is identified as part of routine screening, the following steps are considered:

- The HCW is evaluated promptly for active TB. The initial evaluation includes a thorough history, physical examination, and chest radiograph. On the basis of the initial evaluation, other diagnostic procedures (e.g., sputum examination) may be indicated.

- If appropriate, the HCW should be placed on preventive or curative therapy in accordance with current guidelines (see Appendix A, Supplement 2).

- A history of possible exposure to *M. tuberculosis* is obtained from the HCW to determine the most likely source of infection (see "PPD Conversion Assessment" in Appendix O). When the source of the infection is known, the drug-susceptibility pattern of the *M. tuberculosis* isolate from the source patient should be identified to determine appropriate preventive or curative therapy regimens.

- If the history suggests that the HCW was exposed to and infected with *M. tuberculosis* outside the facility, no further epidemiologic investigation to identify a source in the facility is necessary.

- If the history identifies a probable source of exposure in the facility, contacts of the suspected source patient are identified and evaluated. Possible reasons for the exposure and transmission are evaluated (Table 4 on page 46 of Appendix A may be used as a general guide). If problems are identified, interventions should be implemented to correct these causes, and PPD testing of PPD-negative HCWs should be performed immediately and repeated after 3 months.

  If no additional PPD test conversions are detected on follow-up testing, the investigation can be terminated.

  If additional PPD test conversions are detected on follow-up testing, the possible reasons for exposure and transmission should be reassessed, the appropriateness of and degree of adherence to the interventions implemented should be evaluated, and PPD testing of PPD-negative HCWs should be repeated after another 3 months.

  If no additional PPD test conversions are detected on the second round of follow-up testing, the investigation can be terminated. However, if additional PPD conversions are detected on the second round of follow-up testing, a high-risk protocol should be implemented in the affected area or occupational group, and the public health department or other persons with expertise in TB infection control should be consulted.

- If the history does not suggest that the HCW was exposed to and infected with *M. tuberculosis* outside the facility and does not identify a probable source of exposure in the facility, further investigation to identify the probable source patient in the facility is warranted.

The interval during which the HCW could have been infected should be estimated. Generally, this would be the interval from 10 weeks before the most recent negative PPD test through 2 weeks before the first positive PPD test (i.e., the conversion).

Laboratory and infection control records should be reviewed to identify all patients or HCWs who have suspected or confirmed infectious TB and who could have transmitted *M. tuberculosis* to the HCW.

If this process does identify a likely source patient, contacts of the suspected source patient should be identified and evaluated, and possible reasons for the exposure and transmission should be evaluated as above; interventions should be implemented to correct these causes, and PPD testing of PPD-negative HCWs should be repeated after 3 months. However, if this process does not identify a probable source case, PPD screening results of other HCWs in the same area or occupational group should be reviewed for additional evidence of *M. tuberculosis* transmission. If sufficient additional PPD screening results are not available, appropriate personnel (the Deputy Director for Clinical Care, Medical Director of OMS, Hospital Epidemiology staff, Infectious Disease specialists, and/or affected department heads/supervisors) should consider conducting additional PPD screening of other HCWs in the same area or occupational group.

If this review and/or screening does not identify additional PPD conversions, nosocomial transmission is less likely, and the contact investigation can probably be terminated. Whether the HCW's PPD test conversion resulted from occupational exposure and infection is uncertain; however, the absence of other data implicating nosocomial transmission suggests that the conversion could have resulted from other sources.

If this review and/or screening does identify additional PPD test conversions, nosocomial transmission is more likely. In this situation, the patient identification (i.e., triage) process, TB infection control policies and practices, and engineering controls should be evaluated to identify problems that could have led to exposure and transmission.

If no such problems are identified, a high-risk protocol should be implemented in the affected area or occupational group, and the public

health department or other persons with expertise in TB infection control should be consulted.

If such problems are identified, appropriate interventions should be implemented to correct the problem(s), and PPD skin testing of PPD-negative HCWs should be repeated after 3 months.

If no additional PPD conversions are detected on follow-up testing, the investigation can be terminated.

If additional PPD conversions are detected on follow-up testing, the possible reasons for exposure and transmission should be reassessed, the appropriateness of and adherence to the interventions implemented should be evaluated, and PPD skin testing of PPD-negative HCWs should be repeated after another 3 months.

If no additional PPD test conversions are detected on this second round of follow-up testing, the investigation can be terminated. However, if additional PPD test conversions are detected on the second round of follow-up testing, a high-risk protocol should be continued in the affected area or occupational group, and the public health department or other persons with expertise in TB infection control should be consulted.

2. Investigating Cases of Active TB in HCWs

If an HCW develops active TB, the following steps are taken:

- The case is evaluated epidemiologically, in a manner similar to PPD test conversions in HCWs, to determine the likelihood that it resulted from occupational transmission and to identify possible causes and implement appropriate interventions if the evaluation suggests such transmission.

- Contacts of the HCW (e.g., other HCWs, patients, visitors, and others who have had intense exposure to the HCW) are identified and evaluated for TB infection and disease (See section XI.C below). The public health department should be notified immediately for consultation and to allow for investigation of community contacts who were not exposed in the CC.

- The public health department should notify facilities when HCWs with TB are reported by physicians so that an investigation of contacts can be conducted in the CC. The information provided by the health department to the CC should be in accordance with state or local laws to protect the confidentiality of the HCW.

B. Investigating Possible Patient-to-Patient Transmission of *M. tuberculosis*

Surveillance of active TB cases in patients is conducted as described in Section V.A. If this surveillance suggests the possibility of patient-to-patient transmission of *M. tuberculosis* (e.g., a high proportion of TB patients had prior admissions during the year preceding onset of their TB, the number of patients with drug-resistant TB [outside of MDR-TB protocols] increased suddenly, or isolates obtained from multiple patients had identical and characteristic drug-susceptibility or DNA fingerprint patterns), the following steps are taken:

- Review the HCW PPD test results and patient surveillance data for the suspected areas to detect additional patients or HCWs with PPD test conversions or active disease.

- Look for possible exposures that patients with newly diagnosed TB could have had to other TB patients during previous admissions. For example, were the patients admitted to the same room or area, or did they receive the same procedure or go to the same treatment area on the same day?

If the evaluation thus far suggests transmission has occurred, the following steps are taken:

- Evaluate possible causes of the transmission (e.g., problem with patient detection, institutional barriers to implementing appropriate isolation practices, or inadequate engineering controls) (Table 4 on page 46 of Appendix A may be used as a general guide).

- Ascertain whether other patients or HCWs could have been exposed; if so, evaluate these persons for TB infection and disease (see Section XI.C below).

- Notify the appropriate public health departments so they can begin a community contact investigation if necessary.

C. Investigating Contacts of Patients and HCWs Who Have Infectious TB

If a patient who has active TB is examined in the CC and the illness is not diagnosed correctly, resulting in failure to implement appropriate isolation precautions, or if an HCW develops active TB and exposes other persons in the CC, the following steps should be taken when the illness is later diagnosed correctly:

- To identify other patients and HCWs who were exposed to the source patient before isolation procedures were begun, interview the source patient and all applicable personnel and review that patient's medical record. Determine the areas of the CC in which the source patient was hospitalized, visited, or worked before being placed in isolation (e.g., outpatient areas, and patient lounges) and the HCWs who may have been exposed during that time (e.g., persons providing direct care, therapists, clerks, transportation personnel, housekeepers, and social workers).

- The contact investigation should first determine if *M. tuberculosis* transmission has occurred from the source patient to those persons with whom the source patient had the most intense contact.

- Administer PPD tests to the most intensely exposed HCWs and patients as soon as possible after the exposure has occurred. If transmission did occur to the most intensely exposed persons, then those persons with whom the patient had less contact are evaluated. If the initial PPD test result is negative, a second test is administered 12 weeks after the exposure was terminated.

- Those persons who were exposed to *M. tuberculosis* and who have either a PPD test conversion or symptoms suggestive of TB should receive prompt clinical evaluation and, if indicated, chest radiographs and bacteriologic studies should be performed. Those persons who have evidence of newly acquired infection or active disease should be evaluated for preventive or curative therapy. Persons who have previously had positive PPD test results and who have been exposed to an infectious TB patient do not require a repeat PPD test or a chest radiograph unless they have symptoms suggestive of TB.

- In addition to PPD testing those HCWs and patients who have been exposed to *M. tuberculosis* because a patient was not isolated promptly or an HCW with active TB was not identified promptly, the investigation should determine why the diagnosis of TB was delayed. If the correct diagnosis was made but the patient was not isolated promptly, the reasons for the delay need to be defined so that corrective actions can be taken.

- Examples of memos used in conducting problem investigations (to potentially exposed HCWs and to physicians of potentially exposed patients) are included in Appendix Q.

XII. COORDINATION WITH THE PUBLIC HEALTH DEPARTMENT

- As soon as a patient or HCW is known or suspected to have active TB, the patient or HCW should be reported to the public health department so that appropriate follow-up can be arranged and a community contact investigation can be performed (see Appendix K: Protocols for Coordination With the Public Health Department). The health department should be notified well before patient discharge to facilitate follow-up and continuation of therapy. A discharge plan coordinated with the patient or HCW, the health department, and the CC should be implemented (see Section V.E.7).

- The public health department should protect the confidentiality of the patient or HCW in accordance with state and local laws.

- The CC and health departments should coordinate their efforts to perform appropriate contact investigations on patients and HCWs who have active TB.

- The HES is responsible for reporting results of all cultures positive for *M. tuberculosis*, and drug-susceptibility results on *M. tuberculosis* isolates, to the appropriate health department as soon as these results are available.

XIII. ADDITIONAL CONSIDERATIONS FOR SELECTED AREAS IN THE CC

This section contains additional information for selected areas and settings in the CC.

A. Operating Rooms

- Elective operative procedures on patients who have TB should be delayed until the patient is no longer infectious.

- CDC recommends that if operative procedures must be performed, they should be done, if possible, in operating rooms that have anterooms. For operating rooms without anterooms, the doors to the operating room should be closed, and traffic into and out of the room should be minimal to reduce the frequency of opening and closing the door**.** CC OR suite 11 is planned to be renovated in the near future so that adjacent nonsterile

space is balanced to achieve negative pressure, with exhaust to the outside; therefore, this OR room should be used. Attempts should be made to perform the procedure at a time when other patients are not present in the operative suite and when a minimum number of personnel are present (e.g., at the end of the day).

- Placing a bacterial filter on the patient endotracheal tube (or at the expiratory side of the breathing circuit of a ventilator or anesthesia machine if these are used) when operating on a patient who has confirmed or suspected TB may help reduce the risk for contamination of anesthesia equipment or discharging tubercle bacilli into the ambient air.

- During postoperative recovery, the patient should be monitored and should be placed in a private room that meets recommended standards for ventilating TB isolation rooms.

- When operative procedures (or other procedures requiring a sterile field) are performed on patients who may have infectious TB, respiratory protection worn by the HCW must protect the field from the respiratory secretions of the HCW and protect the HCW from the infectious droplet nuclei generated by the patient. Valved or positive-pressure respirators do not protect the sterile field; therefore a respirator that does not have a valve and that meets the criteria in Section VII should be used. Alternatively, persons working over the surgical field who must wear a PAPR, should wear the longer helmet head piece tucked under their surgical gown, so that the air is exhausted below the surgical field. Other persons in the OR who do not work over the surgical field (such as anesthesiologists), and who must wear a PAPR must wear a surgical mask under the PAPR to trap their respiratory secretions.

B. Autopsy Rooms

- Because infectious aerosols are likely to be present in autopsy rooms, such areas should be at negative pressure with respect to adjacent areas, and the room air should be exhausted directly to the outside of the building. ASHRAE recommends that autopsy rooms have ventilation that provides an airflow of 12 ACH, although the effectiveness of this ventilation level in reducing the risk for *M. tuberculosis* transmission has not been evaluated. Where possible, this level should be increased by means of ventilation system design or by auxiliary methods (e.g., recirculation of air within the room through HEPA filters). The autopsy

suite is negative pressure to surrounding space and exceeds the recommended ACH (See Appendix C).

- Respiratory protection should be worn by personnel while performing autopsies on deceased persons who may have had TB at the time of death.

C. Laboratories

- Laboratories in which specimens for mycobacteriologic studies (e.g., AFB smears and cultures) are processed, are designed in conjunction with recommendations from CDC, NCCLS and the National Institutes of Health.[4]

- Tubercle bacilli may be present in sputum, gastric lavage fluids, cerebrospinal fluid, urine, and in lesions from a variety of tissues. Exposure to laboratory-generated aerosols is the most important hazard encountered. Tubercle bacilli may survive in heat-fixed smears, and may be aerosolized in the preparation of frozen sections and during manipulation of liquid cultures. Sputa and other clinical specimens from suspected or known cases of tuberculosis must be considered potentially infectious and handled with appropriate precautions.[4]

- In the Microbiology Service, Department of Laboratory Medicine, all culturing of specimens for mycobacteria and all manipulations of mycobacteria are conducted at Biosafety Level 3. No animals are utilized. STAT AFB smears are prepared in the specimen processing area in the Class II biosafety cabinet utilizing the bleach concentration technique.[5] After 5 minutes of inactivation of the specimen with an equal volume of 5% sodium hypochlorite solution (undiluted household bleach), the specimen is centrifuged in cytocentrifuge containment cups.

- No animals are used for mycobacterial research in the Clinical Center. The NIH Division of Safety Occupational Safety and Health Branch develops and implements requirements for mycobacterial research conducted in the other buildings.

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[4] CDC/NIH. Agent: *Mycobacterium tuberculosis*, *M. bovis*. In: Biosafety in microbiological and biomedical laboratories. Artlanta: US Department of Health and Human Services, Public Health Service, 1993:95; DHHS publication no. (CDC)93-8395.

[5] Saceanu CA et al: Evaluation of sputum smears concentrated by cytocentrifugation for detection of acid-fast bacilli. J Clinical Microbiol, 1993;31:2371–4.

D. EMS Personnel/ Transport Personnel

- When EMS personnel or others must transport patients who have confirmed or suspected active TB, a surgical mask should be placed, if possible, over the patient's mouth and nose. Because administrative and engineering controls during emergency transport situations cannot be ensured, EMS personnel should wear respiratory protection when transporting such patients. If feasible, the windows of the vehicle should be kept open. The heating and air-conditioning system should be set on a nonrecirculating cycle.

- EMS personnel are included in the OMS TB Surveillance Program, which means they have a baseline PPD test and follow-up testing. They are also included in the follow-up of contacts of a patient with infectious TB.

E. Dental Settings

In general, the symptoms for which patients seek treatment in a dental-care setting are not likely to be caused by infectious TB. Unless a patient requiring dental care coincidentally has TB, it is unlikely that infectious TB will be encountered in the dental setting. Generation of droplet nuclei containing *M. tuberculosis* during dental procedures has not been demonstrated. Therefore, the risk for transmission of *M. tuberculosis* in most dental settings is probably quite low. Nevertheless, during dental procedures, patients and dental workers share the same air for varying periods of time. Coughing may be stimulated occasionally by oral manipulations, although no specific dental procedures have been classified as "cough-inducing." Because the potential exists for transmission of *M. tuberculosis* in dental settings, the following recommendations should be followed:

- The CC dental clinic personnel are included in the CC risk assessment and CC TB control plan.

- While taking patients' initial medical histories and at periodic updates, dental HCWs should routinely ask all patients whether they have a history of TB disease and symptoms suggestive of TB.

- Patients with a medical history or symptoms suggestive of undiagnosed active TB should be referred promptly for medical evaluation of possible infectiousness. Such patients should not remain in the dental clinic any longer than required to arrange a referral. They should be placed in the negative-pressure treatment room in the Dental Clinic (see Appendix C: Rooms with Special Engineering Controls for TB Infection Control) until they can be transferred for medical evaluation. While in the dental clinic and during transport to their evaluation, they should wear surgical masks and should be instructed to cover their mouths and noses when coughing or sneezing.

- Elective dental treatment should be deferred until a physician confirms that the patient does not have infectious TB. If the patient is diagnosed as having active TB, elective dental treatment should be deferred until the patient is no longer infectious.

- If urgent dental care must be provided for a patient who has, or is strongly suspected of having, infectious TB, such care should be provided in the dental clinic negative-pressure treatment room, or the procedure may be done in one of the patient care TB isolation rooms (see Appendix C) Dental HCWs should use respiratory protection while performing procedures on such patients.

- Dental clinic HCWs are included in the OMS TB Surveillance Program and the CC Tuberculosis Control Plan.